#3 P. Brin

Our Reference: ENL-275-A

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE 8-17-01

Applicant:	Andrew Carl Root
Serial Number:	09/918,582
Filing Date:	July 31, 2001
Examiner/Art Group Unit:	Unknown/Unknown
Title:	DEVICE AND METHOD FOR USE IN TAKING MOULDS OF FEET

SUBMITTAL OF PRIORITY DOCUMENT(S)

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

The attorney for Applicant(s) respectfully submits, for filing with the subject patent application, the priority document Great Britain 0102389.4

Respectfully submitted,

YOUNG & BASILE, P.C.

Darlene P. Condra

Darlene P. Condra
Attorney for Applicant(s)
Registration No. 37113
(248) 649-3333

3001 West Big Beaver Rd., Suite 624
Troy, Michigan 48084-3107

Dated: August 17, 2001
DPC/cls.

PATENTS • DESIGNS • COPYRIGHT • TRADE MARKS
The Patent Office

INVESTOR IN PEOPLE

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

Signed

Dated 6 August 2001

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	11
Claim(s)	1
Abstract	
Drawing(s)	6 + 6

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	1
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature Lewis & Taylor Date 30 January 2001

12. Name and daytime telephone number of person to contact in the United Kingdom

Brian Spoor

0116 233 8181

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

a) *If you need help to fill in this form or you have any questions, please contact the Patent Office on 08459 500505.*

b) *Write your answers in capital letters using black ink or you may type them.*

c) *If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.*

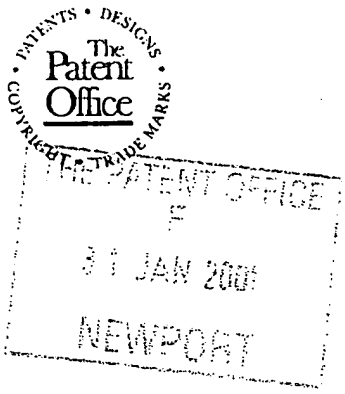
d) *If you have answered 'Yes' Patents Form 7/77 will need to be filed.*

e) *Once you have filled in the form you must remember to sign and date it.*

f) *For details of the fee and ways to pay please contact the Patent Office.*

Patents Form 1/77

Patents Act 1977
(Rule 16)



1/77

31JAN01 E602089-1 D00291
P01/7700 0.00-0102389.4

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
Newport
South Wales
NP10 8QQ

1. Your reference

BS/LP01387UK

2. Patent application number
(The Patent Office will fill in this part)

0102389.4

31 JAN 2001

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Andrew Carl ROOT
Hopyard Farm
Lubbersthorpe
Enderby
Leicestershire
LE9 5AF

Patents ADP number *(if you know it)* 13837402

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

Device and Method for taking moulds of feet

5. Name of your agent *(if you have one)*

Lewis & Taylor

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

144 New Walk
Leicester
LE1 7JA

Patents ADP number *(if you know it)*

711002

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or

b) there is an inventor who is not named as an applicant, or

c) any named applicant is a corporate body.

Title: Device and Method for Taking Moulds of Feet

This invention relates to a device and method for use in the taking of moulds and impressions of feet.

Foot orthotics are an essential part of conservative orthopaedic treatment for correction of biomechanical abnormalities, congenital deformities and abnormal positions acquired through accident or disease processes. The taking of accurate plaster of Paris moulds or three-dimensional impressions of feet is a necessary part of the process of manufacture of foot orthotics.

At present, the plaster of Paris casts and three-dimensional impressions of feet are taken in the following positions:

With a patient sitting with the knee extended, or lying in a prone or supine position, the clinician palpates the subtalar joint to a neutral position with one hand, whilst the remaining hand applies dorsiflexory pressure to the fifth metatarsophalangeal joint or to the plantar surface of the webbing of the fourth and fifth toes.

Alternatively, with a patient sitting with the knee flexed, the foot is allowed to semi-weight bear whilst the clinician maintains the subtalar joint in a neutral position with one hand, as the plaster of Paris bandage hardens or three-dimensional moulding material is placed around the foot.

A major problem with conventional methods of making casts and impressions of feet is their inherent lack of reproducibility. This can lead to the production of ill-fitting orthotics which may be uncomfortable and/or detrimental to the user.

There has now been devised a device and method for use in the taking of moulds and impressions of feet which overcome, or substantially mitigate, the above-mentioned or other disadvantages.

According to a first aspect of the invention, a device for use in the taking of a mould or impression of a foot comprises a generally planar member adapted for abutment with the sole of a patient's foot, and means by which the device may be held in any desired orientation.

According to a second aspect of the invention, a method of taking of a mould or impression of a foot comprises applying to the sole of the foot the planar member of a device as defined above, and holding the device in a desired orientation.

According to a third aspect of the invention, a device for use in the taking of a mould or impression of a foot comprises a generally planar member adapted for abutment with the sole of a patient's foot, and means for detecting angular displacement of the planar member.

According to a fourth aspect of the invention, a method of taking of a mould or impression of a foot comprises applying to the sole of the foot the planar member of a device as defined above, and detecting the angular displacement of the planar member.

In a preferred embodiment, the device according to the invention is provided with angular measurement means and display means, by which angular displacement of the planar member from a datum position can be determined. In one preferred embodiment, such means may be electronic. In such a case, means for setting the display to zero to provide a datum are preferably provided. This means may comprise a button actuatable by the clinician, to facilitate measurement of a given angular displacement from the datum position. Alternatively, the angular measurement and display means comprises a Vernier scale arrangement.

The angular measurement means may comprise means by which movement in degrees of tilt in the frontal plane of the foot may be measured by mechanical and/or magnetic and/or rotational movement. The angular measurement means may, for instance, include means for detecting a reference and means for determining the position of the vertical plane in relation to that reference. The reference may comprise another part of the foot or leg, or may be an external reference such as magnetic north, a mechanical reference means, or may be provided

by means of a gyroscope. A potentiometer may be provided which is rotated when the device is rotated, thereby changing the resistance of the potentiometer. The resultant change in voltage may, after suitable calibration, be converted by digital logic to an output value in degrees which is displayed, e.g. on a liquid crystal display. A separate moving axis may be added to the planar member or built into the planar member to act as a reference point, or a fixed point strapped to the leg or foot or otherwise fixed, e.g. to the patient's chair, may extend to the planar member.

The new device can be used with the patient seated with the knee extended, or with the patient lying in a prone or supine position.

The planar member may be hingedly connected to one or more further planar members to allow separate forefoot and rearfoot movement and first ray movement of the foot to be detected.

The device according to the invention is advantageous primarily in that it facilitates more accurate taking of three dimensional impressions of feet, which is currently carried out manually holding the foot whilst the plaster hardens to form the cast. The accuracy of alignment may be within a single degree or better. The device provides greater stability whilst the mould is being taken and, in preferred embodiments, any movement of the patient's foot or the clinician's hand will be visibly seen on the liquid crystal display, enabling the position to be corrected. This is especially important when taking moulds of children's feet.

The device also reduces or eliminates the need for adding estimated amounts of intrinsic posting to the positive cast, which is time consuming and a major source of inaccuracy in the finished orthosis.

The device may be used for the manufacture of both foot orthoses and ankle/foot orthoses. The device can be used for a three-dimensional impression of a foot, when using impression materials or impression bagging materials which surround the foot, whilst the clinician can check the angular position of the foot at any time.

The device thus improves both the reproducibility and accuracy of three dimensional impressions of feet.

The invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of a preferred embodiment of a device according to the invention using electronic means to detect the tilt movement of the handle and plate;

Figure 2 is a schematic elevation of the device of Figure 1;

Figure 3 shows the electronic circuitry involved in the embodiment of Figures 1 and 2;

Figure 4 is a diagram showing how angular measurements are calculated, using the circuitry of Figure 3;

Figure 5 shows a similar device with a fixed reference point as in Figure 1 but using a vernier scale for detection of angular tilt;

Figure 6 is a plan view of a further embodiment of a device according to the invention;

Figure 7 is a side view of the device of Figure 7; and

Figure 8 shows a modified form of the device of Figures 6 and 7, in use.

Referring first to Figures 1 and 2, a device according to the invention is generally designated at 1. The device 1 comprises a generally planar main body 10 which, in use, is placed on the edge of the chair or couch on which a patient lies or sits, the patient's lower leg being supported by the body 10 with the ankle and foot projecting beyond the body 10. The front

edge of the body 10 is provided with a soft insert 12, which acts as a foot rest for the patient's comfort.

The body 10 has a cranked front portion 14 on which a removable tray 16 is received. The front portion 14 is hingedly connected to the body 10, to allow the device to be folded for ease of transport.

An articulated platform 18 is pivotally mounted to and beneath the front portion of the body 10. Hence, the platform 18 can be rotated about a vertical axis X. The platform 18 includes a planar member 20, which, in use, is brought into contact with the sole of a patient's foot, as described in detail below. Hinges 22, 24, 26 allow movement of the platform 18 about horizontal axes. A handle 28 is fitted to the planar member 20 to facilitate manipulation. Mounted on the planar member 20, above the handle 28 is an electronics unit 30 for measuring angular tilt of the planar member 20. The unit 30 has a liquid crystal display 32, and a zero reset button 34 is incorporated into the handle 28. The button 34 is positioned so as to be operable by the thumb of a user's hand which grasps the handle 28.

In this embodiment, electronics in the form of a potentiometer 36, positioned at the point of pivotal attachment of the platform 18, are used to detect and measure movement of the platform 18 about the vertical axis X, this movement being indicative of the degree of tilt of the planar member 20 about the frontal plane of the foot. A power pack 38 is attached to the underside of the front portion 14, so as to enable the device to be portably operated. The electronics involved, which will be described in more detail later, detects tilt of the planar member 20 to 0.1 degree accuracy, thus enabling the inversion/eversion of the foot to be monitored and closely controlled whist the mould sets. The degree of correction can therefore be set using the digital readout, which is indicative of the frontal plane angle of the foot.

The method for taking subtalar joint neutral casts using plaster of Paris or three-dimensional moulding materials will now be described.

The patient may be in a prone or supine position or sitting up with hip flexed and knee extended as the clinician prefers.

A plaster of Paris bandage is applied to the foot in the usual manner in preparation for the casting position and the patient told to relax the foot completely as the bandage application is completed.

In order to use the device 1, the body 10 is placed on the patient's chair or couch and the patient's leg placed in position. The planar member 20 is then brought into contact with the sole of the patient's foot, which is manipulated, essentially as described below. The tray 16 collects surplus casting material and is easily removed for cleaning (or may be a completely disposable item).

The planar member 20 is held against the plantar surface of the foot by the clinician, and dorsiflexory pressure applied to the handle 28. The clinician ensures that the planar member 20 and the foot are both in line with the leg, then depresses the zero reset button 34 to set a datum position, readable on the display 32, from which the angle of tilt can be measured. The clinician's free hand may then simultaneously palpate the subtalar joint position required by inverting and everting the planar member 20 by the required amount, as indicated on the display 32. The subtalar joint position is then held exactly by maintaining dorsiflexory pressure through the planar member 20. The amount of dorsiflexory pressure applied through the handle 28 against the foot may be varied accordingly. The pressure may be applied to both rearfoot and forefoot simultaneously or forefoot pressure only to prevent any soft tissue compression of the rearfoot. If the forefoot does not become fully plantigrade with dorsiflexory pressure from the planar member the other hand can be removed from palpating the talonavicular joint and used to apply a downward force to the dorsum of the metatarsophalangeal joints thereby making the forefoot plantigrade with the planar member 20. The frontal plane angle of the foot is maintained at all times by checking the liquid crystal display.

The position is maintained until the plaster of Paris bandage hardens, so that the cast can then

be removed without causing deformation of the plaster. If required, the casting procedure is then repeated on the other foot.

In a prone position, where lines have been drawn on the skin to bisect the posterior of the lower leg and to bisect the posterior of the calcaneum, the device 1 may be used to take the cast in either subtalar joint neutral position alone or heel vertical position, or by inverting/everting the planar member 20 from subtalar joint neutral the cast may be taken in the degree of varus/valgus correction required. With heel vertical prone casting, a separate 90° heel vertical marker (not shown) is added to the planar member 20 (e.g. by means of a clip fitting) and simply aligned to a bisection line previously marked on the posterior of the calcaneum whilst applying dorsiflexory pressure via the planar member 20. The thumb of the hand holding the handle 28 depresses the zero degree reset button 34 and in a varus foot the free hand applies downward pressure to the dorsum of the first metatarsophalangeal joint bringing it into contact with the planar member 20. If the foot is in a plantigrade position against the dorsiflexory pressured planar member 20 with the heel vertical marker aligned to the posterior bisection of the calcaneum, increased dorsiflexory pressure may be applied at once to both forefoot and rearfoot simultaneously, or pressure may be applied to the forefoot only to prevent soft tissue compression to the plantar surface of the calcaneum, whilst the marker still maintains heel vertical position. The position is maintained until the plaster hardens or the three-dimensional moulding material has gone evenly around the foot.

When requiring a mould with a degree of correction from subtalar joint neutral, e.g. 4° varus, the subtalar joint neutral position is initially palpated with one hand palpating the talonavicular joint and the other hand inverting and everting the foot with the planar member 20 applying a constant dorsiflexory force to the plantar surface of the foot until neutral position is palpated. The reset button 34 is then depressed. Then the planar member 20 is moved in the frontal plane, increasing the height of the arch, to register 4° on the liquid crystal display 32. The foot has now been corrected by 4° and the cast will harden in 4° of varus correction. Pressure may then be increased to the forefoot by the planar member 20 keeping the same frontal plane degree position, as displayed by the liquid crystal display 32, until the forefoot becomes plantigrade. Alternatively, the hand palpating the talonavicular

joint may be removed (without altering the 4° position of the platform), allowing the apices of the index and third finger of the free hand to apply downward pressure inside the bandage to the dorsum of the first metatarsophalangeal joint, to bring the foot into a plantigrade position with the planar member 20. The cast, when removed, will be in 4° of varus correction from subtalar joint neutral.

Figure 3 is a system block diagram of the electronics circuit used in the embodiment of Figures 1 and 2. The angular displacement of the planar member (20, Figures 1 and 2) is measured by the potentiometer 36. The potentiometer 36 is supplied with a reference voltage 38 across its end terminals and a voltage appears at the potentiometer wiper terminal whose value represents the angle to be measured.

This voltage is measured by an Analogue to Digital Converter 40 which is controlled by a microprocessor 42. The microprocessor 42 reads the voltage and converts it to an angle using a simple proportional calculation. This reading is the uncorrected angle (represented by the symbol Au in Figure 4) of the potentiometer 36. Since the potentiometer 36 has inherent inaccuracies due to its physical characteristics, the microprocessor 42 corrects this reading Au by applying corrections stored in the EEPROM (Electrically Erasable Programmable Read Only Memory, 44). These corrections are calculated during the production calibration phase of the device, by comparing the reading Au against a known accurate reference angle measuring device (not shown). These comparisons are made typically every 5 degrees and the corrections are stored in the EEPROM. EEPROM memory is non-volatile, i.e. its data is retained even when power is removed form the circuit.

Referring also to Figure 4, when the microprocessor reads the uncorrected angle Au, it also reads the correction factor for this angle (as described above) and applies it to the reading Au (typically using a linear interpolation algorithm) to create a corrected reading, Ac.

This angle Ac represents the absolute angle of the planar member relative to the body of the device. This angle is not suitable for displaying to the user as it does not represent the angle of the foot in a readily understandable format. To produce a reading that represents the angle

of the foot in degrees relative to the line of the leg, the fixture is set so that the planar member is exactly in line with the leg line. At this point, the user (for example the calibrator, or clinician) presses the zero degree reset button 34, as indicated in Figures 1 and 2. At this point the microprocessor notes the angle measured (the 'absolute null' denoted by Az, and corrected using the correction data in the EEPROM as before). The relative angle of the planar member can then be determined by subtracting the corrected angle Ac from the null angle Az. The resulting angle, denoted Af, can therefore be positive or negative and represents the angle of the foot base from the line of the leg.

The user may also want to be able to set a 'local null', Al, at some position other than the 'absolute null', Az. When the planar member is at the required position, the user re-presses the reset button 34 to obtain a 'local null' reading. Alternatively, a second switch may be provided for this 'local null' reading function. The local angle, denoted by As, is then displayed on liquid crystal display 32, as indicated in Figures 1 and 2, relative to the 'local null' by subtracting Ac from the local null Al. The angle of the planar member relative to the leg line 'absolute null' Af is also displayed to the user. To ensure that the system retains its settings when the unit is powered down, the local null and absolute null values are stored in the EEPROM.

The device may be provided with a communication link to an external computer, to allow transfer of data and/or parameters, for example patient information, patient treatment history, historical data or calibration curves. This link may take the form of a parallel or serial data port. Measurements may then be stored in or transferred from a patient database, for example to be compared with measurements from previous treatment sessions.

Turning now to Figure 5, a device according to this embodiment of the invention is generally designated 50. The device 50 comprises a generally planar main body 51 which, in use, is placed on the edge of the chair or couch on which the patient lies or sits, the patient's lower leg being supported by the body 50 with the ankle and foot projecting beyond the body 51. The body 51 is padded for the patient's comfort.

The body 51 has a cranked end portion 52 on which a removable tray 53 is received. An articulated platform 54 is pivotally mounted beneath the end portion 52, such that the platform 54 can be rotated about a vertical axis. The platform 54 includes a planar member 55, which, in use, is brought into contact with the sole of a patient's foot, generally as described in detail above. Hinges 56, 57, 58 allow movement of the platform 54 about horizontal axes. A handle 59 is fitted to the planar member 55 to facilitate manipulation.

Angular movement of the platform 54 about the vertical axis is monitored by means of a Vernier scale on adjustment knobs 60, 61.

The device 50 is used in a broadly similar manner to the embodiment described above. The body 51 is placed on the patient's chair or couch and the patient's leg placed in position. The platform 54 and the patient's foot are then manipulated, essentially as described above, the degree of correction being set using the Vernier. The tray 53 collects surplus casting material and is easily removed for cleaning (or may be a completely disposable item).

Referring now to Figures 6 and 7, a hand-held device according to this embodiment of invention is generally designated 62 and comprises a base 63 with a handle 64. The base 63 is a rigid plate of approximate thickness 3mm having a planar face 65, and may be formed integrally with the handle 64 by moulding in plastics material. Two spring-loaded lips 66 are provided laterally of the handle 64, for retaining the edges of a paper towel wrapped around the underside of the base 63.

Mounted on the base 63, above (as viewed in Figure 6) the handle 64, is an electronics unit 67 which incorporates a means for measuring angular tilt of the base. The unit 67 has a liquid crystal display 68, and a zero reset button 69 is incorporated into the handle 64. The button 69 is operable by the thumb of the user's hand which grasps the handle 64.

The electronics unit 68 includes means for detecting the an external reference from which the degree of tilt of the base can be calculated. For example, the electronics unit 68 may include means for detecting magnetic north, and/or a rotational potentiometer which is rotated when

the base 63 is rotated, thereby changing the resistance of the potentiometer. The resultant change in voltage is converted by digital logic circuitry to an output value in degrees which is displayed on the liquid crystal display 68. Alternative means for detecting the tilt of the base may be provided by a mechanical reference means or by means of a gyroscope.

In order to use the device 62, a clean paper towel is placed over the base 63 and folded back and inserted under the raised clips 66. A plaster of Paris bandage is applied to the foot in the usual manner, in preparation for the casting position, and the patient told to relax the foot completely as the bandage application is completed.

The surface 65 of base 63 is then brought into contact with the sole of the patient's foot and the method for taking subtalar joint neutral casts is then carried out, substantially as described above.

The device of Figure 8 (generally designated 70) is similar to that described with reference to Figures 6 and 7, in that it comprises a base platform 71 having a planar surface 72, and a handle 73. An electronics unit 74 with an LED display (not visible) is mounted on the platform 71 above the handle 73, and a reset button 75 is provided to zero the display.

The device 70 differs from that of Figures 6 and 7 in that it is provided with a reference arm 76 which is pivotally connected to the platform 71. The free end of the arm 76 bears against the patient's lower leg. The point at which the arm 76 is pivotally connected to the platform 71 includes means (not shown in detail) which are operably linked to the electronics unit 74, by which the angle of the arm 76 relative to the platform 71 can be measured. The arm 76 provides a fixed point relative to which the angle of tilt of the platform can be measured.

Claims

1. A device for use in the taking of a mould or impression of a foot, the device comprising a generally planar member adapted for abutment with the sole of a patient's foot, and means by which the device may be held in any desired orientation.

2. A method of taking of a mould or impression of a foot the method comprising applying to the sole of a patient's foot a planar member as claimed in claim 1 a device as defined above, and holding the device in a desired orientation.

3. A device for use in the taking of a mould or impression of a foot, the device comprising a generally planar member adapted for abutment with the sole of a patient's foot, and means for detecting angular displacement of the planar member.

4. A method of taking of a mould or impression of a foot comprises applying to the sole of a patient's foot a planar member as claimed in claim 3 and detecting the angular displacement of the planar member.

Fig. 1

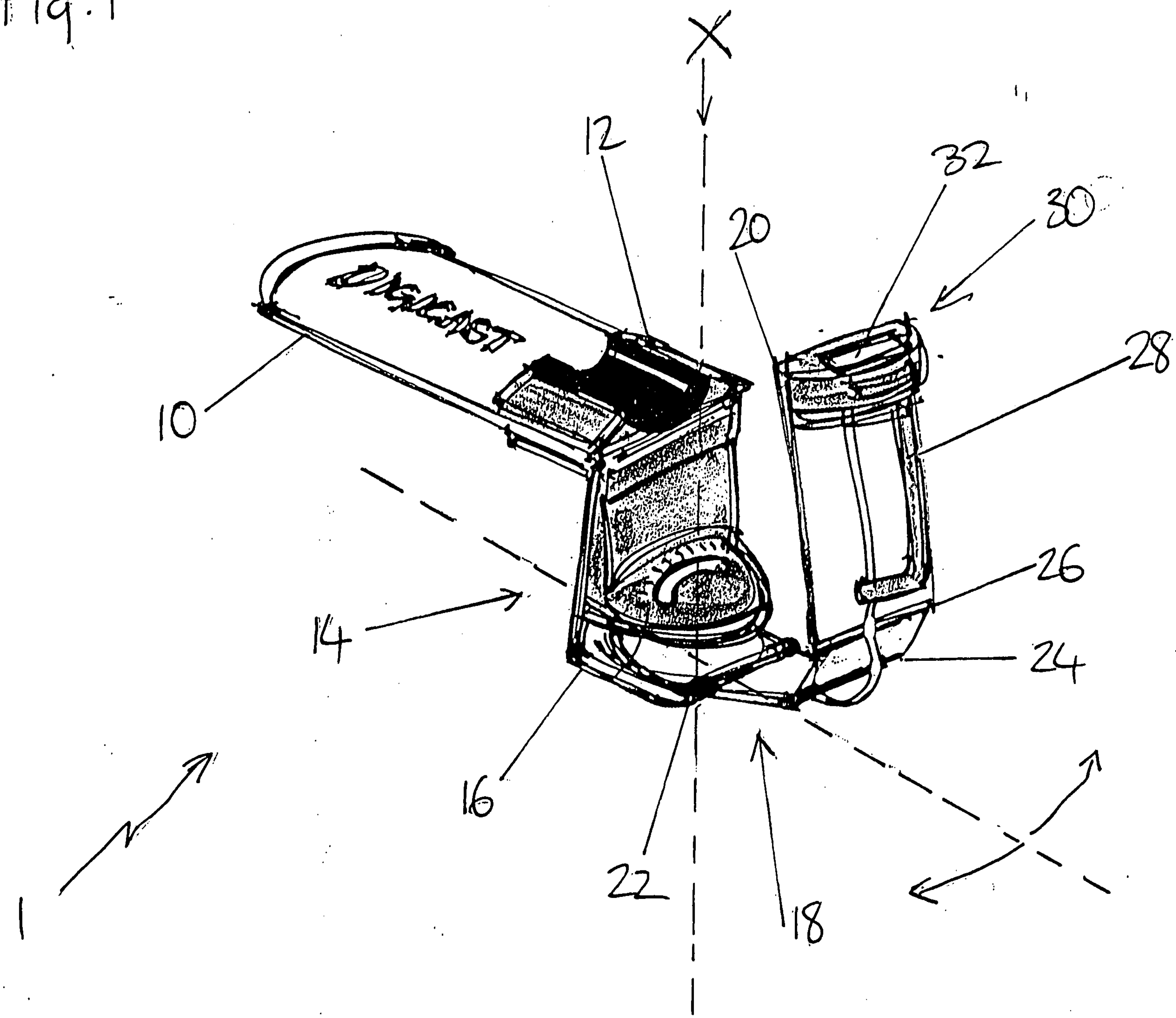


Fig.2

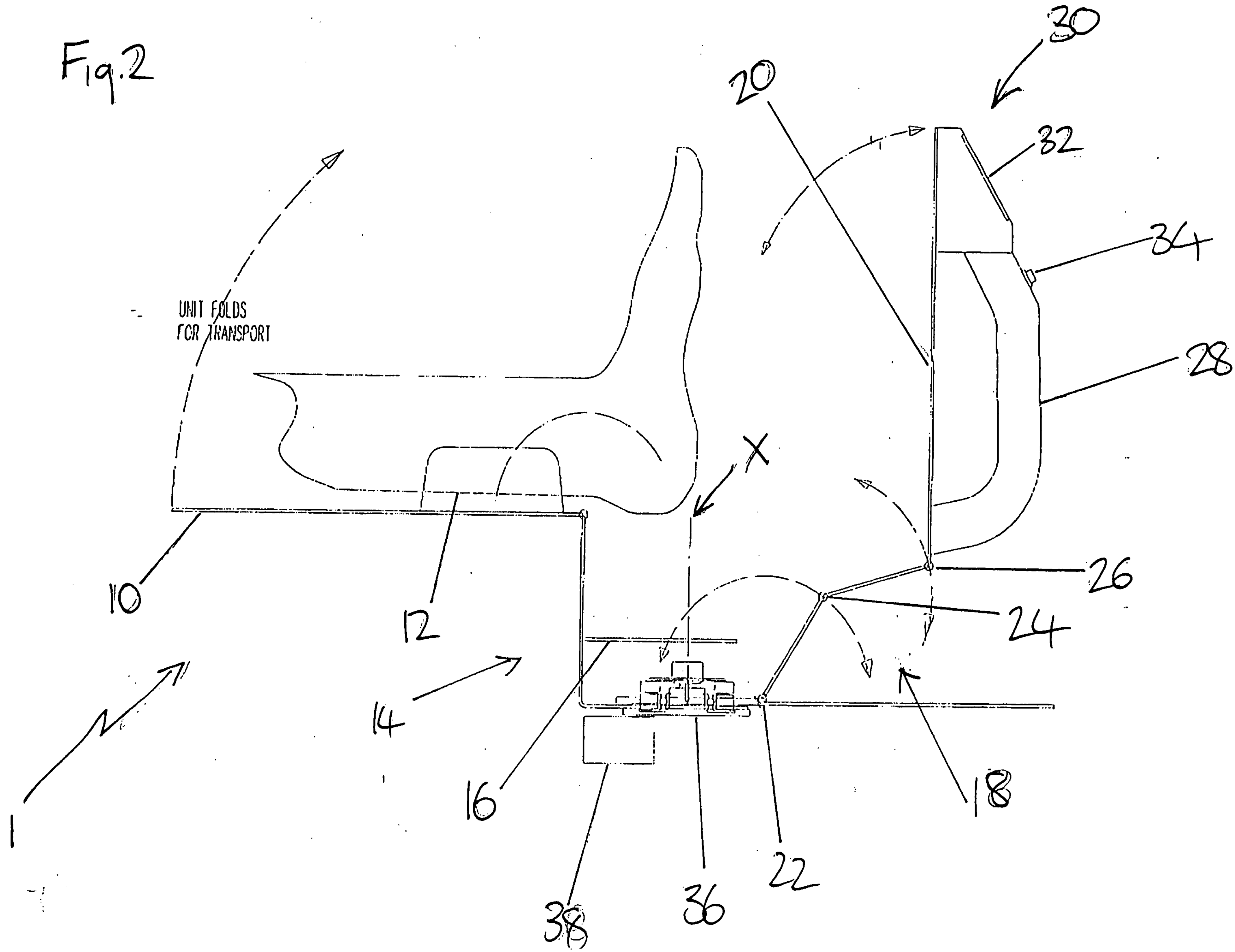

30
20
32
34
UNIT FOLDS
FOR TRANSPORT
28
X
10
12
26
24
14
16
18
1
22
36
38

Fig 3

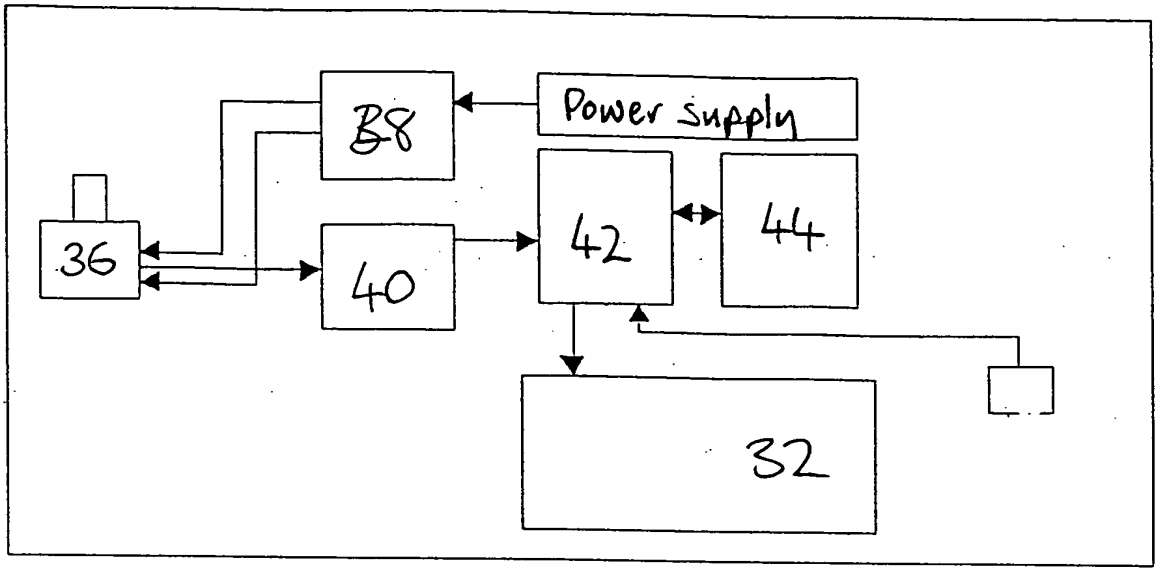
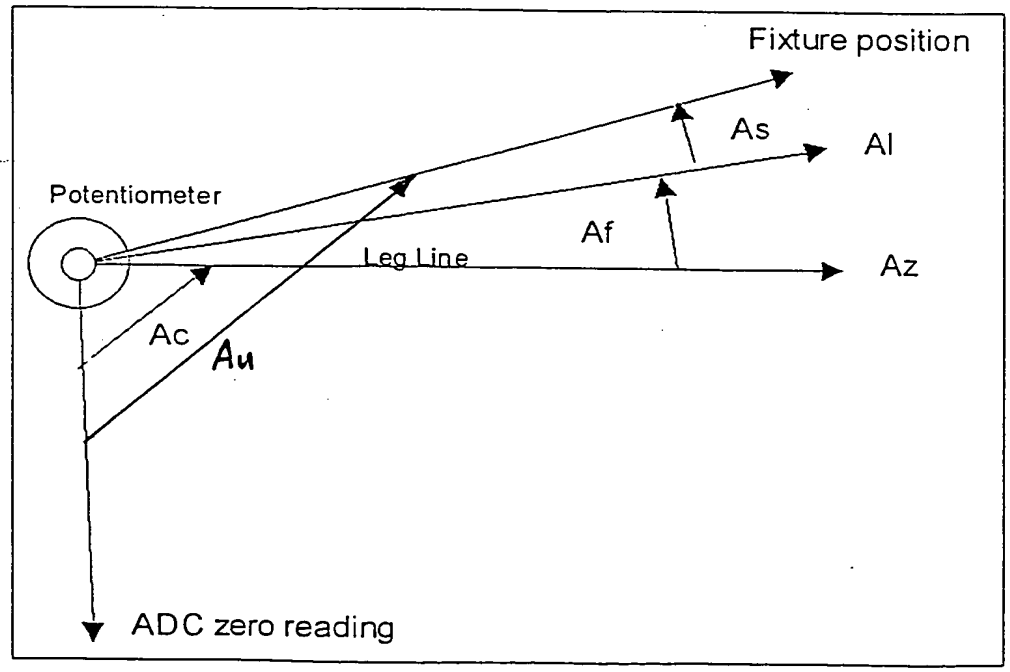

38
Power supply
36
40
42
44
32

Fig 4


Fixture position
As
Al
Potentiometer
Af
Leg Line
Az
Ac
Au
ADC zero reading

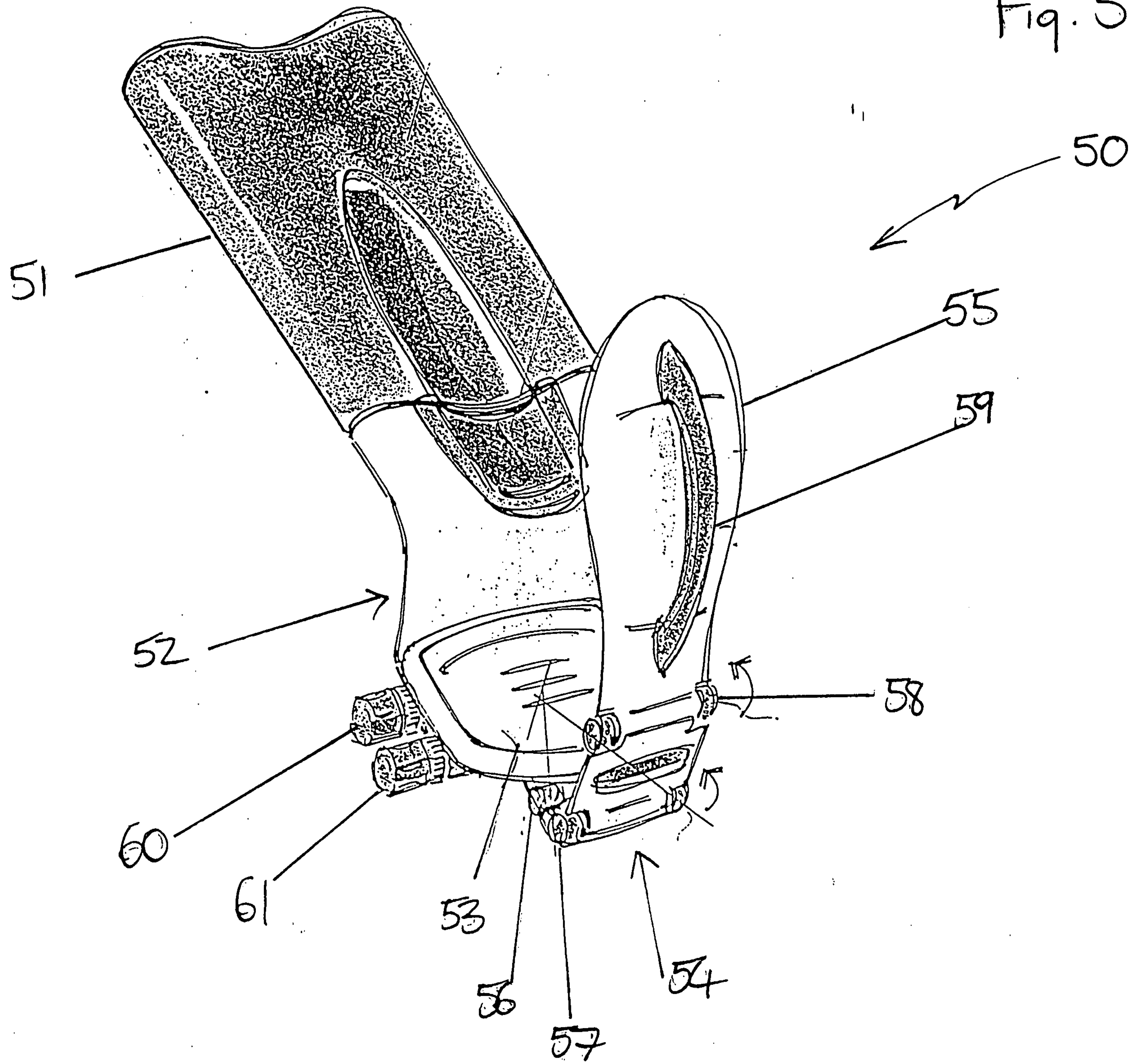
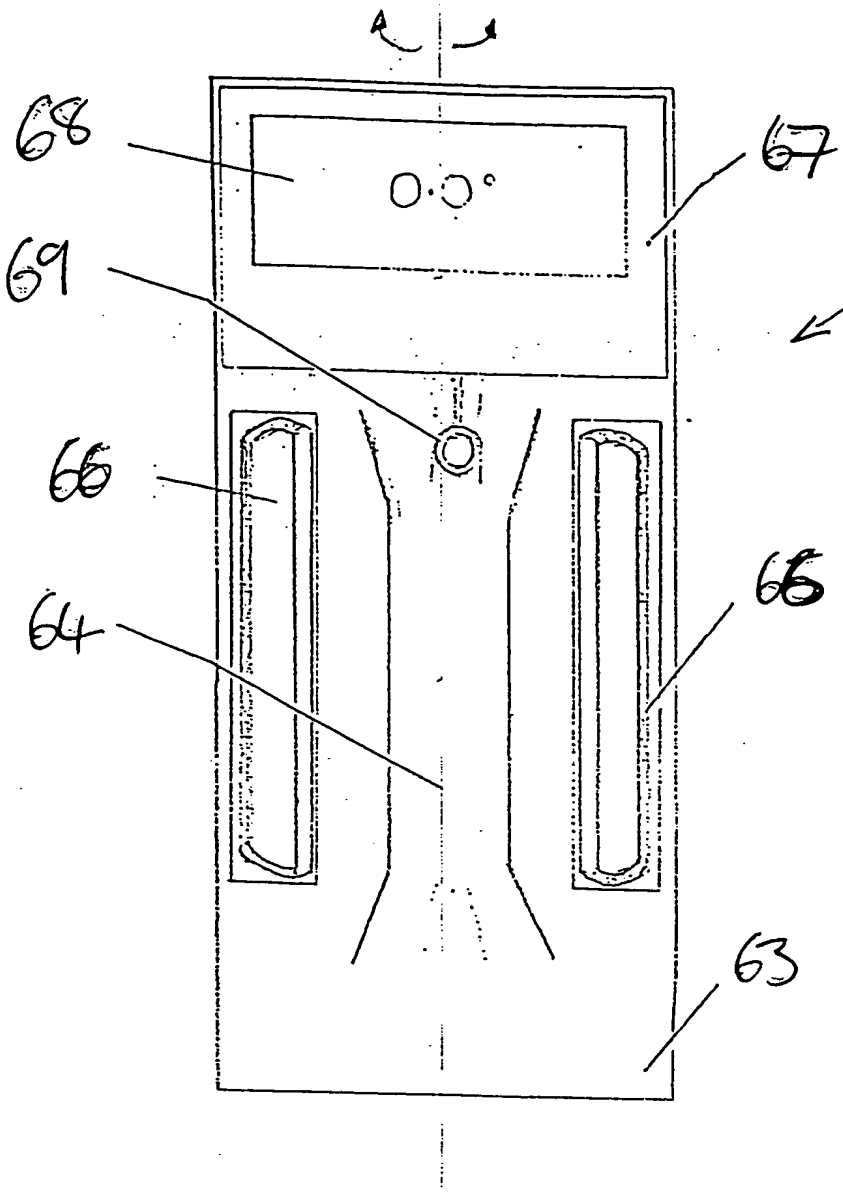


Fig. 5

Fig. 6



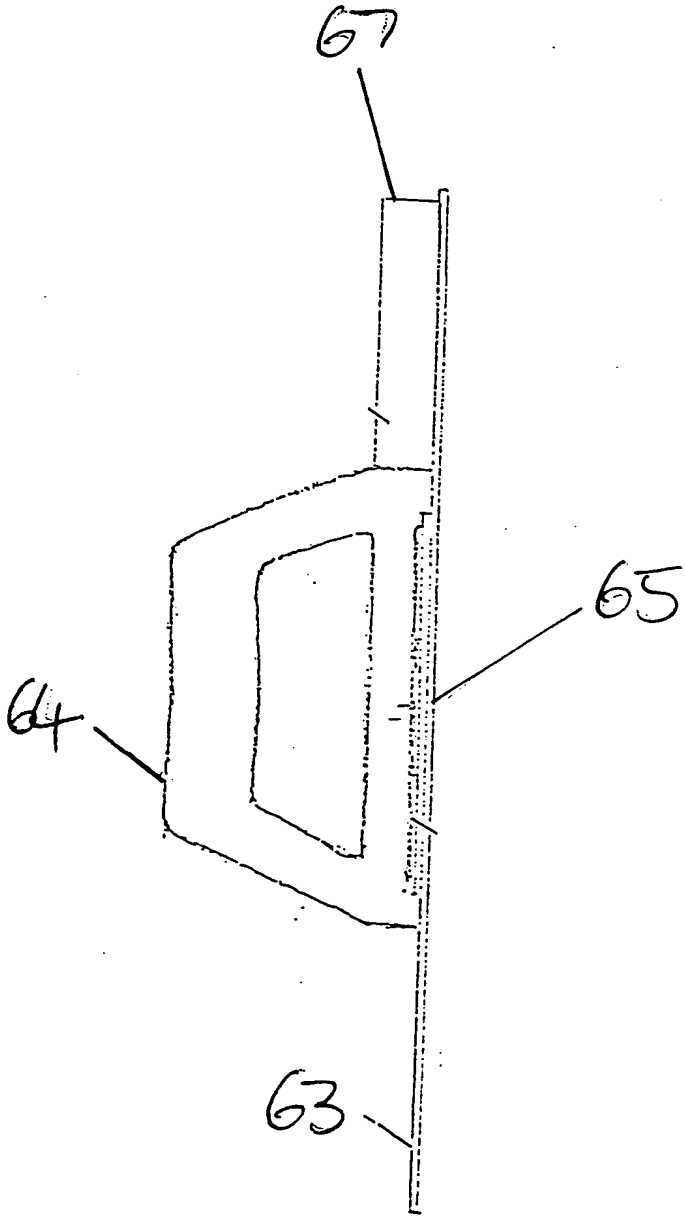


Fig. 7

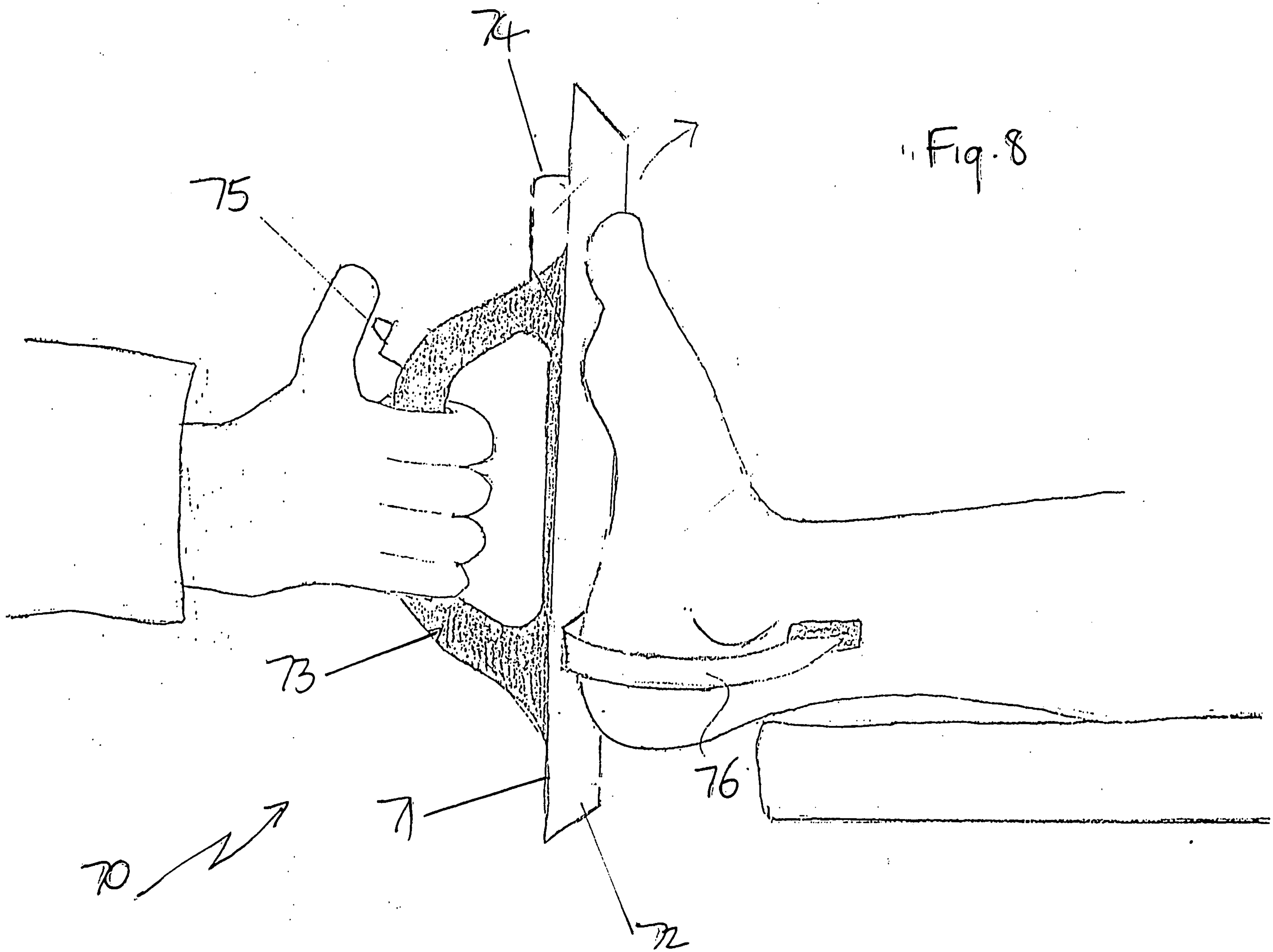


Fig. 8